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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/686,020	10/10/2000	Jennifa Gosling	19934000710	4696

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EXAMINER	
BUNNER, BRIDGET E	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 09/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/686,020	GOSLING ET AL.	
	Examiner	Art Unit	
	Bridget E. Bunner	1647	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 09 August 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on *04 August 2004*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *33-37 and 44-48*.

   Claim(s) withdrawn from consideration: *38-43*.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Continuation of 5. does NOT place the application in condition for allowance because:

IClaims 33-37 and 47-48 are rejected under 35 U.S.C. § 112, first paragraph (enablement). Applicant asserts that the Office dismisses the guidance on appropriate dosage levels in the instant specification. Applicant argues that the Office has not backed up its own assertions with acceptable evidence or reasoning. Applicant's arguments have been fully considered but are not found to be persuasive. Specifically, the dosage guidance disclosed in the specification is not specific to any particular disease or any particular agent. Undue experimentation would be required by the skilled artisan to determine the appropriate dosages of all possible agents for any number of conditions. Undue experimentation would also be required of the skilled artisan to identify individuals with a CCX Chemokine Receptor-mediated condition. Such trial and error experimentation is considered undue. Regarding the the issue that undue experimentation is required to identify agents with a desired activity, Applicant indicates that the Baggiolini reference states that testing for chemokine antagonists is simple and that certain model systems for studying various diseases associated with chemokines were known as of the priority date of the application. Applicant contends that in addition to the specific agents provided in the specification, a reasonable number of additional active agents could have been identified by the skilled artisan using routine methods. Applicant states that the specification provides guidance in the identification of agents. Applicant's arguments have been fully considered but are not found to be persuasive. Baggiolini teaches that testing for chemokine antagonists is simple and mostly polycyclic compounds have been identified in blind screening programs (pg 101, the bottom of col 1 through the top of col 2). The claims of the instant application recite administering any agent that inhibits or promotes binding (i.e., any antagonist or agonist). Additionally, the claims encompass the administration of all possible agents, including nucleic acid molecules, antibodies, proteins, and other organic and inorganic substances. A large quantity of experimentation would be required of the skilled artisan to test all possible agents for a specific activity and then administer that agent to treat all possible CCX chemokine receptor-mediated conditions. Furthermore, Applicant asserts that Baggioloini supports Applicant's view that the skilled practitioner armed with the knowledge provided in the specification concerning CCX CKR ligands could have readily obtained agents without undue experimentation. Applicant notes that the specification identifies over 30 chemokines or chemokine related molecules that are not ligands for CCX CKR. Applicant states that the specification thus provides considerable guidance on the direction that research should not proceed. Applicant's arguments have been fully considered but are not found to be persuasive. There is little guidance in the specification to identify all possible agents, including nucleic acid molecules, antibodies, proteins, and other organic and inorganic substances that have a desired activity and then administer those agents to treat a CCX CKR-mediated condition. It is also not clear where the specification discloses molecules that are not ligands for CCX CKR. The Examiner has interpreted that this information is disclosed in Figure 4a. A large quantity of experimentation is still required by the skilled artisan to test an infinite number of agents (including nucleic acid molecules, proteins, antibodies, organic and inorganic compounds) for a desired activity and then administer that agent to treat a CCX CKR-meditated condition. Finally, Applicant asserts that a role for CCX CXR in various inflammatory conditions is fully consistent with the activity of other chemokines. Applicant's arguments have been fully considered but are not found to be persuasive. The art acknowledges that function cannot be predicted based solely on structural similarity to another protein. Therefore, one skilled in the art would not be able to predict that CCX CKR plays a role in inflammation and undue experimentation would be required to determine such.

Claims 33-37 and 44-48 are also rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s) at the time the application was filed, had possession of the claimed invention. Applicant asserts that sufficient description has been provided with respect to three distinct classes of agents within the claimed genus. No substantially new arguments have been presented, and thus the rejections are maintained for reasons of record.

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER